



United States of America  
FEDERAL TRADE COMMISSION  
Washington, DC 20580

Annette Soberats  
Division of Advertising Practices  
202-326-2921; asoberats@ftc.gov

July 12, 2022

**VIA ECF**

Hon. Louis L. Stanton, U.S.D.J.  
U.S. District Court-S.D.N.Y.  
500 Pearl Street  
New York, NY 10007

RE: *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.* (17-CV-00124-LLS)  
Plaintiffs' Request for *Daubert* Briefing

Dear Judge Stanton:

Pursuant to Rule 2.A. of Your Honor's Individual Practices, Plaintiffs, the Federal Trade Commission and the Office of the Attorney General of the State of New York, respectfully request that the Court grant them leave to file a motion under Federal Rules of Evidence 403 and 702, as well as *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and its progeny, to exclude opinions of Defendants' seven experts on various grounds, including those set forth below.<sup>1</sup> Because these experts offer opinions that are irrelevant, unreliable, and not grounded in their expertise, the Court should use its gatekeeping power to prevent Defendants from offering testimony that would mislead the jury rather than educate it. *See FTC v. Vyera Pharms., LLC*, No. 20cv00706 (DLC), 2021 WL 5336949, at \*3 (S.D.N.Y. Nov. 16, 2021); *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 469 (S.D.N.Y. 2018).

**Defendants' Experts Offer Improper Legal Conclusions That Are Outside Their Expertise, Within the Purview of the Court to Decide, and Based on Irrelevant and Erroneous Legal Conclusions.** Most of Defendants' experts offer opinions regarding the appropriate legal standard for substantiating the advertising claims made in this case. Specifically, Defendants' experts argue that a randomized controlled trial is not required to substantiate the challenged claims, based on a legal interpretation of the Dietary Supplement Health & Education Act of 1994 (enforced by the FDA) and FTC law and guidelines. Defendants' experts base their opinions on law, rather than any scientific expertise. These opinions are inadmissible.

First, these experts are not legal or regulatory experts and therefore are unqualified to offer such opinions. To the extent that Defendants wish to make legal arguments, they must make them to the Court and let the Court decide.

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<sup>1</sup> Given that Defendants have seven experts who offer a wide range of impermissible opinions, Plaintiffs' letter-motion highlights only some of Plaintiffs' proposed *Daubert* challenges.

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Second, opinions about the appropriate legal standard are generally impermissible, as they do not constitute “scientific knowledge,” do not have a reliable basis in any scientific discipline, and impermissibly intrude upon the duty of the Court to instruct the jury with regard to the applicable law. *See In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d at 469.

Third, Defendants’ experts’ legal opinions are simply wrong. They are based on erroneous interpretations of FDA evidentiary standards, the FTC Act, and an FTC guidance document aimed at explaining the law to marketers, *Dietary Supplements: An Advertising Guide for Industry*. With respect to FDA evidentiary standards, the law is clear they are irrelevant in a case involving liability for deceptive advertising under the FTC Act and parallel New York statutes. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d. Cir. 1984) (“Insofar as FDA requirements and regulations are concerned, they simply do not govern this case.”); *FTC v. Wellness Support Network, Inc.*, No. 10-4879, 2013 WL 5513332, at \*10 (N.D. Cal. Oct. 4, 2013) (FDA classification of a product as a drug or medical food was irrelevant; granting FTC’s motion to exclude testimony of expert as it did not constitute “scientific knowledge”). Even if FDA standards were relevant, they are consistent with the applicable legal standard in this case, which is the type of evidence that experts in the relevant field would consider competent and reliable. With respect to the FTC Act and guidance, which *is* the relevant standard in this case, courts look to experts in the relevant *scientific* field to establish the scientific standard.

Defendants’ experts’ opinions about the evidence necessary to substantiate the challenged claims, as well as the sufficiency of Defendants’ proffered substantiation, are based not on science, but on their flawed interpretation of the law. Their conclusions are *not* based on any evaluation of what type of evidence experts in the relevant fields of memory and cognition would require. As a critical step of their reasoning is based not on the scientific method, but on flawed legal interpretations, Defendants’ experts’ substantiation analysis is unreliable and inadmissible. *See Amorgianos v. Amtrak*, 303 F.3d 256, 267 (2d. Cir. 2002).

**Dr. Kurzer Lacks Expertise to Testify About Memory, Cognitive Function, and the Clinical Significance of Defendants’ Substantiation.** Dr. Kurzer, a professor of nutrition, concedes that she is not an expert in cognitive function or statistics. She lacks training and clinical experience in any fields related to memory or cognitive function. Her opinions on memory and cognition, as they relate to Prevagen and its ingredients, rest on articles written by others, on issues for which she offers no expertise of her own. Dr. Kurzer simply has no adequate qualifications to offer competent testimony on memory and cognitive function, the clinical significance of study results or treatment, and whether Vitamin D or apoeaquorin (Prevagen’s active ingredients) supplementation improves memory and cognition. It is well established that a witness may not offer expert testimony on subjects in which she lacks expertise. *See Shea v. Long Island R.R. Co.*, No. 05-cv-9768 (LLS), 2009 U.S. Dist. LEXIS 43748, at \*2 (S.D.N.Y. May 20, 2009).

**Dr. Katz Lacks Expertise to Testify About a Re-Analysis of the Madison Memory Study Using the Seemingly Unrelated Regressions (“SUR”) Econometric Model.** During his deposition, Dr. Katz conceded that he “profess[es to have] no specific expertise in this analytical method,” and had never used the SUR model before being retained for this matter. The bases of his opinions about the SUR model are conversations he had with one of the economists who conducted the SUR re-analysis. “[A] proffered expert may not simply pass off as [his] own, or

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serve as a vehicle for presenting, the opinions of others in subjects on which the proffered expert is not personally qualified.” *Hart v. BHH, LLC*, No. 15-CV-4804, 2018 U.S. Dist. LEXIS 12131, at \*23 (S.D.N.Y. July 19, 2018); *see also Louis Vuitton Malletier v. Dooney Bourke, Inc.*, 525 F. Supp. 2d 558, 664-66 (S.D.N.Y. 2007) (excluding testimony based solely on statistical analysis of consulting expert that testifying expert was not qualified to conduct or interpret).

**Dr. Goodman Lacks Expertise to Testify About Apoeaquorin, and His Discussion of Allergens Should be Excluded as Unreliable.** Dr. Goodman seeks to opine that apoeaquorin, a dietary protein, might have a therapeutic effect, but he bases his opinions on proteins that are allergens, and thus, have vastly different properties from those of apoeaquorin. Dr. Goodman lacks expertise on dietary protein absorption and bioactivity outside the context of allergens and celiac peptides and therefore cannot opine on how apoeaquorin is digested or absorbed, or whether a particular amount of apoeaquorin could have a therapeutic effect. Second, Dr. Goodman speculates about how peptides might have bioactive properties, but this sort of testimony is irrelevant and misleading because he has not cited evidence that apoeaquorin produces any peptides in digestion, let alone bioactive ones. This kind of testimony would not serve to assist the jury, and should, therefore, be excluded. *See Au New Haven v. Ykk Corp.*, No. 15-cv-3411, 2019 U.S. Dist. LEXIS 45044, at \*10-11 (S.D.N.Y. Mar. 19, 2019).

**Dr. Gortler’s Discussion of Alleged Calcium-Binding Effects of Apoeaquorin and Unrelated Drugs Should Be Excluded as Irrelevant and Misleading.** Dr. Gortler seeks to testify about calcium’s relationship to Alzheimer’s disease, and about apoeaquorin’s calcium-binding effect in the brain. Such testimony is unreliable and irrelevant because apoeaquorin is not offered to treat Alzheimer’s disease, and apoeaquorin has not been shown to cross the human blood-brain barrier. Dr. Gortler’s speculative testimony therefore lacks sufficient reliability to be presented to the jury. Moreover, Dr. Gortler, who has not conducted any study or analysis on the absorption or effect of apoeaquorin in humans, seeks to opine that a number of drugs, compounds, and microorganisms might have some effect on the body – without determining whether these drugs, compounds, and microorganisms have similarities to apoeaquorin.

**Defendants’ Experts Should Be Precluded From Testifying Without Reviewing the Relevant Data.** Defendants’ experts’ testimony should be excluded where it does not rely on sufficient facts or data. *See Fed. R. Evid. 702(b); United States v. Chang*, No. 18-cr-501, 2020 U.S. Dist. LEXIS 10778, at \*5 (E.D.N.Y. Jan. 21, 2020). For example, Dr. Gortler opined about the Madison Memory Study, but later conceded that he cannot offer an opinion about it and did not review the study’s underlying data. He should therefore be precluded from testifying about it.

**Drs. Kurzer, Schwartz, and Katz Should Be Precluded From Discussing Apoeaquorin’s Potential Mechanisms of Action.** Dr. Kurzer concedes that she opines about potential theories based on references that are not related to apoeaquorin. Dr. Schwartz concedes that he would only be speculating about apoeaquorin’s potential mechanisms of action. And Dr. Katz confirmed that he is not taking a position on potential mechanisms of action. They should all therefore be precluded from offering such misleading and irrelevant testimony.

For the foregoing reasons, Plaintiffs request that the Court grant them leave to file a *Daubert* motion to exclude the opinions of Defendants’ experts on various grounds.

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Respectfully,

/s/Annette Soberats

Annette Soberats, Attorney  
Federal Trade Commission

/s/ Kate Matuschak

Kate Matuschak  
Assistant Attorney General  
New York State Office of  
the Attorney General

cc: All parties via ECF